

# **Use of LEU Produced Mo-99 in the Manufacture of TechnoLite® Generators**

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# Lantheus Medical Imaging

## Headquarters:

**North Billerica, Massachusetts**

- Manufacturing and Distribution
- R&D, Clinical and Medical Affairs
- Sales & Marketing

## Offices:

**Puerto Rico, Canada, Australia**

## Marketed Products:

**8 (radiopharmaceuticals and imaging agents)**

## Products in Clinical and Pre-clinical Development Phases:

**3 (imaging agents – PET and MR )**



# Lantheus Product Portfolio

**DEFINITY**  
VIAL FOR (Perflutren Lipid Microsphere)  
INJECTABLE SUSPENSION

**Techne****Lite**  
Technetium Tc 99m  
Generator

**Cardiolite**  
Kit for the Preparation of  
Technetium Tc99m Sestamibi for Injection

**Xenon Xe 133 Gas**

**Thallium**

Thallous Chloride  
TI 201 Injection

**NEUROLITE**  
Kit for the Preparation of  
Technetium TC99m Bicisate for Injection

**ABLAVAR**  
gadofosveset trisodium

**Gallium**  
Gallium Citrate  
Ga 67 Injection

**Lantheus**  
Medical Imaging

# Lantheus LEU Leadership

- **FIRST** – to receive FDA approval for LEU Mo-99 in North America:
  - ANSTO: June 2009, May 2011
  - NTP: September 2010
- **FIRST** – to commercially sell a generator made with only LEU Mo-99 (December 2010)
- **FIRST** – to have LEU Mo-99 as a routine part of blended Tc-99m production (May 2011)
- **FIRST** – to commercially ship a CMS non-HEU add-on payment compliant generator (Jan. 7, 2013)



Lantheus Medical Imaging  
adds the innovative  
**LEU TechneLite®**  
(Technetium Tc 99m Generator)  
to our Nuclear  
Medicine Portfolio

**Available NOW!**



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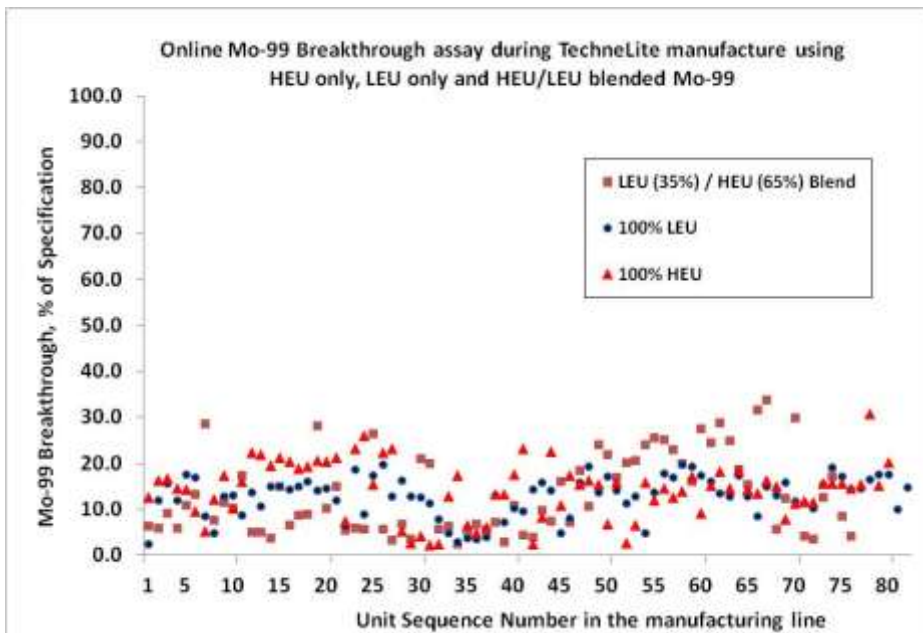


# LEU TechneLite® Manufacture

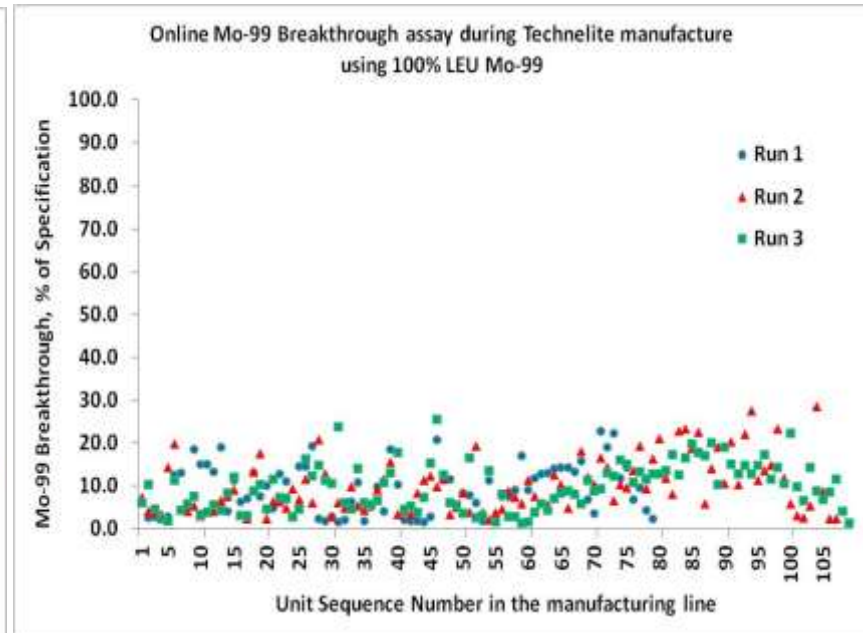
- **LEU TechneLite® generators manufactured in a dedicated weekly run on Monday**
- **Validated cleaning process after each run ensures manufacture line is clean and no carryover of HEU Mo-99 can occur (always < 5%)**
- **TechneLite® LEU generators marked as eligible for CMS add-on payment by circular green sticker affixed to top of generator can**
- **All aspects of LEU Technelite® generators including product insert and labeling are identical to blended or HEU generator**
- **LEU TechneLite® generator segregation and identification:**
  - manufacturing batch records - different code for LEU Mo-99 than HEU Mo-99
  - specific catalog/item number in the Lantheus product catalog (18000-ML versus 18000-M for HEU generator)
  - identifying item number is also on packing, shipping documents and invoice
  - lot number unique identifier – with an “A” incorporated (non-HEU generator - M123456A)



# Mo-99 Breakthrough during Commercial TechneLite® Manufacture Runs



Mo-99 breakthrough for manufacture runs using 100% HEU, 100% LEU and blended HEU/LEU sourced Mo-99

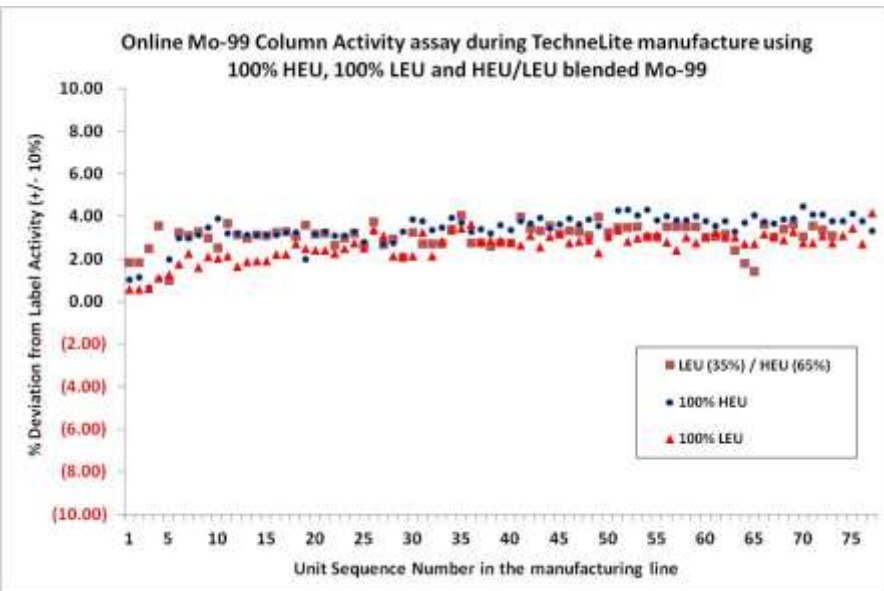


Mo-99 breakthrough for three manufacture runs using 100% LEU sourced Mo-99

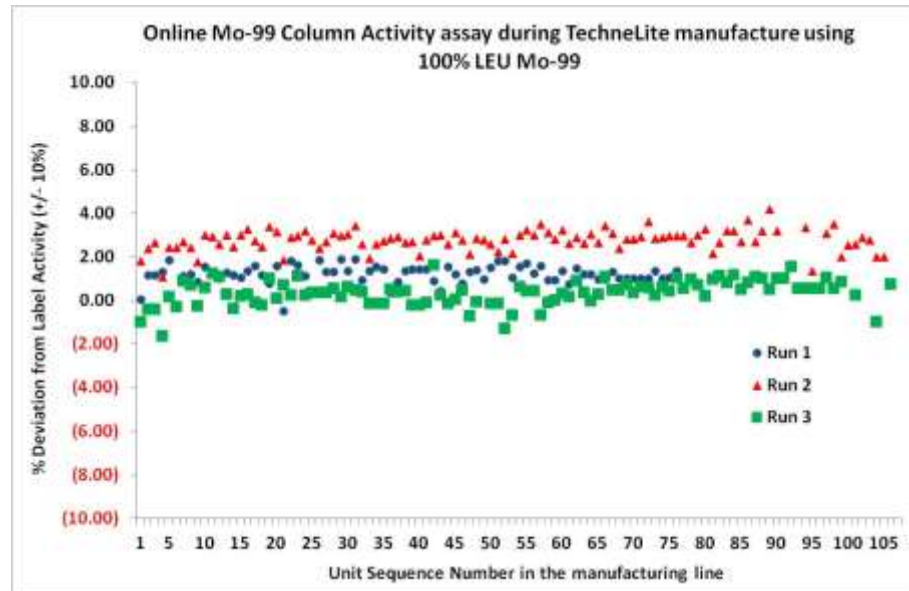
\* 100% of units assayed for Mo-99 breakthrough\*



# Mo-99 Column Activity during Commercial TechneLite® Manufacture Runs



Column assays for manufacture runs using 100% HEU, 100% LEU and blended HEU/LEU sourced Mo-99



Column assays for three manufacture runs using 100% LEU sourced Mo-99

\* 100% of units assayed for column activity \*

# Lantheus LEU Generator Status

- LMI has performed 12 LEU TechneLite® generator runs in 2013
- LMI actively educating customers on LEU Mo-99 myths vs. facts
- LMI working in tandem with key customers to implement LEU generator usage, beginning to see some increase in sales
- LEU Mo-99 will comprise about one-third of LMI Mo-99 purchased in 1Q 2013
- New LMI contract with NTP/ANSTO (through 2017) will significantly increase percentage LEU Mo-99 in 2014-15
- LMI currently plans to be at 100% LEU Mo-99 generators by end of 2016

# Conclusions

- **Quality and properties of LEU TechneLite® generators equivalent to HEU or blended LEU/HEU Mo-99 generators**
- **Tc-99m produced from > 95% LEU content Technelite® generators meets the USP specification**
- **Lantheus has taken a leadership role in use of LEU Mo-99 in its Technelite® generator supply chain**
- **Production of LEU Technelite® generators promotes transition toward goal of all-LEU Mo-99 supply chain by end 2016**
- **Contributes to enhanced global nuclear security and creates foundation for more secure, reliable future supply of Mo-99**

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